UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA

Hartsville Anesthesia Associates, PA, a South Carolina Professional Association, and Advanced Pain Therapies, LLC, a South Carolina Limited Liability Company, **Plaintiffs,** **v.** **XAVIER BECERRA, In his Official Capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HUMAN SERVICES (HHS).** **Defendants.**	**Case No.:** 3:24-cv-04280-MGL **INITIAL COMPLAINT**

INITIAL COMPLAINT

Plaintiffs, Hartsville Anesthesia Associates, PA (Hartsville Anesthesia"), and Advanced Pain Therapies, LLC ("Advanced Pain"), by and through their undersigned counsel, bring this action against Xavier Becerra, in his official capacity as Secretary of Health and Human Services hereinafter referred to as "Secretary" and, the United States Department of Health and Human Services ("HHS") and state as follows:

PRELIMINARY STATEMENT

1. Plaintiffs escalate this matter to this Federal Court pursuant to 42 CFR §405.1132(b) Plaintiffs filed a Request for Escalation to the Medicare Appeals Council pursuant to 42 CFR 1132(a). Plaintiffs' Request for Escalation was ignored by the Medicare Appeals Council and a copy of this Request for Escalation is attached hereto as Exhibit 1.

2. This appeal is limited only to the adverse findings of the Administrative Law Judge, S. Alexander Liu's decision for Part B Medicare claims and the previous suspension of Hartsville Anesthesia's billing privileges. A copy of ALJ Liu's decision OMHA Appeal No.: 3-7457357490 is attached as Exhibit 2.

3. ALJ Liu's decision correctly found that Plaintiffs' Provider William Odom, MD was a principal investigator in National Clinical Trial 01979367 properly registered through Medicare at www.clinicaltrials.gov pursuant to National Coverage Determination (NCD) 310.1 which governs clinical trials.

4. ALJ Liu's decision correctly upheld Plaintiffs' participation in the national clinical trial for the claims at issue.

5. ALJ Liu's decision incorrectly held the Plaintiffs' charges for all nerve blocks performed pursuant to CPT code 64450 subject to local coverage decision (LCD) from outside the Plaintiffs' jurisdiction with Medicare.

6. Based upon the National Coverage Determination 310.1, the binding case law of the federal district and circuit courts prohibiting the utilization of non-binding rules and regulations and the exhaustive evidence submitted in favor of these claims below, the Provider is entitled to a favorable decision for those claims at issue with the exception of the two claims inappropriately billed and at minimum a waiver of any liability for the same.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this civil action pursuant to 42 CFR §405.1132(b). Plaintiffs, Hartsville Anesthesia, is a Professional Association, and Advanced Pain is a South Carolina Limited Liability Company operating in or about Columbia. Thus, venue is proper in the United States District Court, District of South Carolina pursuant to 42 CFR 1136(b)(1)

8. The amount in controversy exceeds $100,000.00. Jurisdiction is appropriate pursuant to 42 CFR 405.1006(c)

PARTIES

9. Plaintiffs are the Providers on appeal. Plaintiffs are South Carolina entities.

10. Defendant, Xavier Becerra in his official capacity as Secretary of Health and Human Services is the proper Defendant to this action pursuant to 42 CFR 1136(d)

BASIS FOR DISAGREEMENT WITH ALJ DECISION

11. At the time of the services rendered which are the subject of the appeal in question, the Provider was a participant in a Clinical Trial Policy entitled The Study of Neurological Ischemia Lower Extremity Pain and Swelling (NCT #01979367) ("CTP"). This CTP was properly enrolled in the Medicare Clinical Trials Registry at clinicaltrials.gov.

12. The provider was audited by the Medicare Contractor Palmetto, GBA, which subsequently made a final demand for the sums at issue here in claiming that the trial was invalid. All Medicare beneficiaries which were receiving treatment through the trial had their care terminated by the Medicare Contractors actions. These Medicare beneficiaries lost valuable treatment and suffered accordingly.

13. The qualified independent contractor continued with the findings of invalidity of the trial and treatment. The Medicare beneficiaries treatment continue to be lost.

14. The ALJ correctly found that the CTP was properly certified as in compliance with NCA 310.1 for inception as of August 2012 and certified by a principal investigator involved therein to comply with and pursuant to NCD 310.1 (Routine Costs in Clinical Trials).

15. The principal component services of the CTP were monochromatic infrared photo energy (MIRE) in combination with electronic signal treatment (TENS) therapy, together with small pain fiber (spf) nerve conduction studies (ncs) utilized to determine if an impairment is present and utilized to objectively indicate when affected small pain fibers are functioning within normal range.

16. A final component is nerve block injections which may be utilized to control pain until such time the above-described therapies effectively replace the need for additional pain control measures.

17. Each principal investigator will make decisions regarding the treatment needs and frequency of their participating patients. *See* protocol for the CTP developed by Doctors Testing and Study Centers, LLC in coordination with and on behalf of the AASEM sponsoring organization. This is found at clinicaltrials.gov and on the record on appeal ("ROA").

18. Each item or service of the CTP are routine costs typically provided in the absence of clinical trials to Medicare beneficiaries, as reflected by the CTP codes assigned by Medicare and utilized throughout by the Provider below.

19. The National Coverage Determination governing clinical trials is NCD 310.1. The ALJ below recognized this fact within the decision on appeal.

20. With regard to routine costs such as the nerve block injection category billed under CPT code 64450 which comprised 467 of the 481 claims at issue, these claims are covered as a routine cost under the NCD if they meet the definition of routine costs in said NCD.

21. NCD 310.0 defines routine costs as follows:

"Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national coverage determination)"

22. Regarding the 467 claims for nerve block injections under CPT code 64450, the ALJ does not dispute there is a benefit category therefore the first criteria is met. The ALJ's decision refers to absolutely no statutory exclusion for said treatment (i.e., there is none).

23. The ALJ's decision recognizes there is no national coverage determination against the utilization of nerve blocks for the treatment of severe pain. At this point, the ALJ's analysis should have concluded with a favorable decision.

24. Unfortunately, the decision completely ignores the definition of routine costs contained in said NCD. The ALJ violated statutory interpretation rules and due process rules laid down in several court decisions by reaching out to an LCD of another jurisdiction and applying the same.

25. The Federal Courts have dealt extensively with appeals from the Medicare Appeals Counsel to the District Courts based on the misapplication of CMS rules or in this case, regulations from another jurisdiction. *See Caring Hearts v. Burwell* 824 F. 3rd 968(10th Cir. 2016) and *Cypress Home Healthcare v. Azar,* 326 F. Supp. 3d (E.D. Tex. 2018).

26. In this matter, ALJ Liu directly contradicted the rules laid down in both Cypress Home Healthcare and Caring Hearts by applying a much more stringent version contained in an LCD that did not apply in the jurisdiction in which the Provider practiced. *"For surely one thing no agency can do is apply the wrong law to the citizens that come before it..."* Caring Hearts at 970-971.

27. The utilization of the LCD is prohibited by case law and also prohibited because the NCD 310.1 controlled the very issue to be decided. LCDs are subordinate to NCDs. Once the criteria of the NCD were satisfied for the reimbursement of these study claims, the analysis should have concluded with a favorable ruling.

28. The first key error in the ALJ's analysis was the initial deviation from the language of the NCD defining routine costs. Clearly, the 467 claims at issue met the definition of routine costs previously described above in the NCD 310.1. The application of the outside jurisdiction LCD and the analysis followed by the ALJ completely ignored the language of the NCD and constituted the second key error.

29. Routine costs in clinical trials include:

- *Items or services that are typically provided absent a clinical trial (i.e., conventional care);*
- *Items or services required solely for the provision of the investigational item or service (i.e., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and*
- *Items or services needed for reasonable and necessary care arising from the provision of an investigation\al item or service – in particular, for the diagnosis or treatment of complications.*

30. Each of the claims in the ROA contains the medical documentation to support the necessity of treating the chronic pain (i.e., complications) that arose during the clinical trial protocol. The Provider, Dr. William Odom, testified at the hearing from the medical records for each beneficiary concerning how this pain arose, its duration, and the ultimate resolution of said pain through the utilization of the trial protocol.

31. The Provider also testified about the need for nerve blocks as the best medical choice. Indeed, the only choice for the beneficiaries at issue.

32. A Final Agency Decision in Living Well PDX was affirmed by the District Court in and for Oregon *Living Well PDX, PC v. United States Department of Human Services* No. 3:21-cv-01074-AR (D. Or. Jan. 10 2024) found that the Clinical Trial at issue in this case and the propriety of billing injections to control pain has been found reimbursable and is precedential in this matter.

33. At the final hearing conducted by the ALJ below, the Provider called two experts in addition to the treating physician, Dr. William Odom, to testify. The first expert Mr., Sean Weiss, CHC, CEMA, CMCO, CPMA, CPC-P,CMPE, CPC is an expert in Medicare rules and regulations and certified in coding. Mr. Weiss has testified on behalf of Medicare on many occasions and on behalf of providers on many occasions.

34. Mr. Weiss's firm reviewed the medical records in this matter and Mr. Weiss testified on several topics at the hearing.

35. Mr. Weiss provided his expert opinion that the claims billed under CPT code 64450 complied with the National Coverage Determination 310.1 and were fully supported by the medical records submitted below. His testimony was detailed concerning these issues. Mr. Weiss further testified there were no LCDs that affected reimbursement for the claims and no LCDs that could affect reimbursement of the claims since the same were governed by the clinical trial NCD 310.1.

36. As part of the clinical trial services, only the Chief Medical Officer of Medicare could invalidate the clinical trial protocols and charges thereunder pursuant to NCD 310.1.

37. Mr. Weiss testified extensively regarding the fourteen claims on appeal considered invalid due to the result of "altered documentation".

38. Mr. Weiss testified that many of the claimed alterations were nothing more than corrections to the written record and that said corrections were obvious and initialed. With regard to all other inclusions on the record, they consisted of doctor's notations placed into the margin with regard to future treatment.

39. Mr. Weiss testified this was entirely appropriate medical record keeping. Further, such notations had nothing to do with the treatment rendered at the time and the documentation of such. There were merely notes from the physician with regard to reminders to be considered in further treatments.

40. This testimony was entirely consistent with the Provider's testimony (Dr. William Odom) regarding the medical services.

41. Mr. Weiss and the Provider's credentials and testimony were unquestioned regarding the same facts. All notations questioned in the record were addressed by both experts and completely explained in the record.

42. The ALJ failed to note this testimony or give any reason to deviate from its accuracy. The ALJ's opinion regarding medical record-keeping was wholly unsupported in the ROA.

43. A further reason given by Mr. Weiss and provided to the ALJ for not deviating from the NCD was the Medicare Claims Processing Manual (Internet Only) ¶32 §69.4 which states as follows:

¶ 32 §69.4-Local Medical Review Policy

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Do not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.

All of this testimony and rules were ignored by the ALJ.

44. The second expert was Dr. Boyer. Dr. Boyer reviewed all medical records for the thirty patients at issue in this appeal.

45. Dr. Boyer was a principal investigator for the clinical trial under which these services were rendered.

46. Dr. Boyer testified that the medical records were of very high quality concerning the treatment rendered and testified regarding the use of nerve block injections under CPT code 64550 and their absolute necessity in the context of the services and claims on appeal.

47. As a physician, Dr. Boyer clearly understood from reviewing the records and from the content of the records the reasons the Provider utilized the injections and the medical necessity of the same.

48. This testimony correlated with the testimony of the Provider, Dr. William Odom. Dr. Odom explained in detail all thirty charts in his testimony as contained in the ROA.

49. All experts provided their opinions that the treatment rendered was reflected in the medical records on appeal, the records themselves were above and beyond adequate

under medical record-keeping standards and the treatment provided at issue (i.e., injections under CPT 64450) were medically reasonable and necessary and were routine costs covered by Medicare under NCD 310.1.

50. The decision on appeal contains zero references to the expert testimony provided during the hearing and zero attempts to distinguish said testimony. In point of fact, there was no contrary evidence submitted during the hearing and no appearance by the Qualified Independent Contractor ("QIC") in defense of its decision.

51. Of the 481 claims at issue for thirty patients, there were two claims that appear to be improperly billed by the third-party billing contractor. The Provider acknowledged this mistake and conceded the same.

EVALUATION OF EVIDENCE

52. In determining whether to grant reimbursement in this case one must consider the axiom that "the congressional policy underlying the federal social security legislation requires the courts to interpret the Act liberally, and any doubts should be resolved in favor of coverage" Herbst v. Finch, 473 F.2d 771,775)2d Cir. 1972); accord, Gold v. Secretary, 463 F.2d 38 (2d Cir. 1972); Rasmussen v. Gardner, 374 F 2d 589 (10th Cir. 1967); Sowell v. Richardson, 319 F.Supp. 689 (D.C.S., 1970); Lord v. Richardson, 356 F. Supp. 232 (S.D.lnd. 1972). The Act should be construed to effectuate its overriding purpose even if the words used leave room for a contrary interpretation." Haberman v. French, 418 F2d 664 (2dCir. 1969).

WAIVER

53. At a minimum, the Provider is entitled to a waiver of liability in this matter. Clearly, the Provider was involved in a valid clinical trial that had been affirmed by agency final decisions dating back to before its involvement with the same. Section 1870 of the Social Security Act provides the authority for waiver of overpayments and other payment adjustments for incorrect payments on behalf of individuals.

54. The statute provides that the overpayment shall not be recovered from the Provider if "without fault" or where such recoupment "would be against equity and good conscience". See also 42 C.F.R. §§ 405.350 & 405.355.

55. Section 1879 of the Social Security Act provides that when Medicare excludes payment and coverage pursuant to Section 1862(a)(l) of the Act, payment may nevertheless be made for the items or services, if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that that the items or services would to be covered or payable by Medicare. See also, 42 C.F.R. § 411.406.

56. It is clear from the facts of these cases and the information provided that the Provider would qualify as without fault and would have good reason to believe these claims to be covered and payable.

57. The existence of the Clinical Trial Policy is simply one more basis which has been reaffirmed through ALJ Judge Faulkner and through several QIC reconsideration decisions as providing final agency decisions in favor of this Provider on the very same treatment under the very same circumstances as the claims currently at issue herein. At the extreme minimum, this Provider would qualify under the waiver provisions above.

58. In Cypress Home Care, the 5th Circuit Court of Appeals overturned the Medicare Appeals Counsel determination that waiver of liability should not apply to the provider. The 5th Circuit held the providers' understanding of the applicable law at the time services were rendered" was reasonable and had a basis in the statute and regulations in effect at the time." Dr. Odom was acting exactly as the provider in Cypress Home Care.

59. The very purpose of the waiver provision of §1395pp is to protect providers and beneficiaries from recovery when they have acted in good faith and could 'not have known' the claim was not covered.

COUNT I

Plaintiffs re-allege and reincorporate paragraphs 1-59 above as though fully set forth herein. Plaintiffs, seek to have those aspects of Judge Liu's decision that are unfavorable to Plaintiffs, reversed for the reasons and grounds set forth herein and for the reasons set

forth in Plaintiffs' appeal to the Medicare Appeals Council. These grounds are in addition to those set forth in the record on the appeal required to be delivered by the Department.

PRAYER FOR RELIEF

A. Plaintiffs respectfully request this Court enter an order reversing the analysis and decision-making of Judge Liu and finding that all claims submitted for CPT code 64450 were proper and reimbursable for medically reasonable services.

B. Immediately overturn the suspension of Plaintiffs' billing privileges.

C. Grant such other relief as the Court shall deem proper.

D. Award attorney's fees due the Provider's counsel pursuant to Medicare guidelines and pursuant to 42 CFR 405.910(f).

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CERTIFICATE OF SERVICE

The undersigned certifies that the following were served with a copy of the foregoing document on the date and by the method of service identified below:

CM/ECF

All counsel of record

Dated: July 31, 2024